From: "Kramer, Niklas -521 BMG" <Niklas.Kramer@bmg.bund.de>
To: "Lьcking Dr., Gesa -611 BMG" <Gesa.Luecking@bmg.bund.de>
"Korr Dr., Gerit Solveig -614 BMG" <GeritSolveig.Korr@bmg.bund.de>
"Rexroth, Ute" <RexrothU@rki.de>
Date: 4/14/2021 9:24:50 AM
Subject: AW: Genesenenzertifikate
Attachments: st07552.en21.pdf
citizen_recovery-interoperable-certificates_en.pdf

Liebe Kollegen/innen,

Danke fur die Hinweise, die ich an das IBM Projekt weitergeben werde.
Anbei der aktuelle Stand der VO und des Datensatzes.

Ich bitte um Berucksichtigung und nochmalige Prufung des Erwagungsgrundes 32 und Art. 7.

Die Hinweise von Frau Rexroth erscheinen mir doch, korrigieren Sie mich bitte, hypothetischer Natur zu sein, ich vermute, dass Intensivpatienten in einem Krankenwagen gerade keine Genesenen-Zertifikate erhalten, auch wenn der EU-Rahmen die Berucksichtigung der Symptomatik ggf. nicht explizit macht (letzteres konnen wir im Ubrigen auch noch einbringen).

Ich lese es so, dass die Datenelemente Gultigkeit grundsatzlich von den Mitgliedstaaten bestimmt werden, grundsatzlich werden aber Mindestvorgaben gemacht (Mindestens 11 Tage und maximal 180 Tage, also 6 Monate).
Zudem hat die EU-KOM die Moglichkeit uber delegierte Rechtsakte Anderung der Lange der Gultigkeit der Zertifikate zu bestimmen sowie ggf. die zugrundeliegenden Tests auszuweiten basierend auf Beratungen im HSC und durch das ECDC. Die MS verbleiben frei, daruber zu entscheiden, ob sie diese zur Lockerung von Reisebeschrankungen anerkennen, sie mussen diese jedoch grundsatzlich ihren Burger/innen anbieten.

Erwagungsgrund 32
A certificate of recovery should be issued at the earliest from the eleventh day after the first positive test and should be valid for not more than 180 days. According to ECDC, recent evidence shows that despite shedding of viable SARS-CoV-2 between ten and twenty days from the onset of symptoms, convincing epidemiological studies have failed to show onward transmission of disease after day ten. According to ECDC, recent evidence shows that despite shedding of viable SARS-CoV-2 between ten and twenty days from the onset of symptoms, convincing epidemiological studies have failed to show onward transmission of disease after day ten. The Commission should be empowered to change this period on the basis of guidance from the Health Security Committee or from ECDC, which is closely studying the evidence base for the duration of acquired immunity after recovery."

Article 7 Certificate of recovery
1. Each Member State shall issue, upon request, certificates of recovery as referred to in Article 3(1)(c) at the earliest from the eleventh day after a person has received his or her first positive test for SARS-CoV-2 infection.
The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the number of days as of which a certificate of recovery may be issued, based on guidance received from the Health Security Committee in accordance with Article 3(6) or on scientific evidence reviewed by

ECDC.
The certificate of recovery shall contain the following categories of personal data:
(a) identification of the holder;
(b) information about past SARS-CoV-2 infection following a positive test;
(c) certificate metadata, such as the certificate issuer or a unique certificate identifier.
The personal data shall be included in the certificate of recovery in accordance with the specific data fields set out in point 3 of the Annex.
The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 3 of the Annex by adding, modifying or removing data fields on the categories of personal data mentioned in this paragraph, including until when a certificate of recovery shall be valid, where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate, in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.
3. The certificate of recovery shall be issued in a secure and interoperable format as provided for in Article 3(2).
3a Based on guidance received pursuant to Article 3(6), the Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the provisions in Article 3(1)(c) and Article 7(1) to allow for the issuance of the certificate of recovery also based on a positive rapid antigen test, serological testing for antibodies against SARS-CoV-2 or any other scientifically validated method. Any such delegated act shall add, modify or remove the data fields on the categories of data included in the certificate. The issuance and acceptance of the certificate of recovery based on the tests and methods mentioned in this paragraph shall be optional.
4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.
5. Where Member States accept proof of recovery from SARS-CoV-2 infection as a basis for waiving restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID -19, they shall accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation.

Mit freundlichen Gru?en
Im Auftrag

Niklas Kramer
Referent

_____

Referat 521 - Grundsatzfragen der gematik, Telematikinfrastruktur und eHealth
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-----Ursprungliche Nachricht-----
Von: Lucking Dr., Gesa -611 BMG
Gesendet: Mittwoch, 14. April 2021 08:45
An: Korr Dr., Gerit Solveig -614 BMG <GeritSolveig.Korr@bmg.bund.de>; 'Rexroth, Ute' <RexrothU@rki.de>
Cc: Bartels Dr., Cornelius - 614 BMG <Cornelius.Bartels@bmg.bund.de>; Kramer, Niklas -521 BMG <Niklas.Kramer@bmg.bund.de>; Ramirez Dr., Michaela -611 BMG <Michaela.Ramirez@bmg.bund.de>
Betreff: AW: Genesenenzertifikate

Liebe Gerit, liebe Ute,

das Zertifikat soll "fruhestens" nach dem 11 Tag ausgestellt werden. Da wir fur die Rechtsfolgen verantwortlich sind - d.h. was darf man mit dem Zertifikat in DEU - konnen wir festlegen, dass dieses ungultig ist fur Patienten, die nach DEU med. aufgrund COVID-19 evakuiert werden.

Viele Gru?e,
Gesa

-----Ursprungliche Nachricht-----
Von: Korr Dr., Gerit Solveig -614 BMG <GeritSolveig.Korr@bmg.bund.de>
Gesendet: Mittwoch, 14. April 2021 08:18
An: 'Rexroth, Ute' <RexrothU@rki.de>
Cc: Lucking Dr., Gesa -611 BMG <Gesa.Luecking@bmg.bund.de>; Bartels Dr., Cornelius - 614 BMG <Cornelius.Bartels@bmg.bund.de>; Kramer, Niklas -521 BMG <Niklas.Kramer@bmg.bund.de>
Betreff: Genesenenzertifikate

Liebe Ute,

guter Punkt, wir nehmen das mit in die Diskussionen auf. Ich setze die Kollegen, die damit ebenfalls befasst sind, cc.

Herr Kramer, konnen Sie mir bitte einmal den aktuellen Stand (aktueller Entwurf) schicken?

Vielen Dank
Gerit Korr

-----Ursprungliche Nachricht-----
Von: Rexroth, Ute <RexrothU@rki.de>

Gesendet: Dienstag, 13. April 2021 22:51
An: Korr Dr., Gerit Solveig -614 BMG <GeritSolveig.Korr@bmg.bund.de>
Betreff: pauschale Genesenenzertifikate?

Liebe Gerit,

Wegen des Genesenenzertifikats ist mir noch aufgefallen: Wenn Frankreich oder die EU diese pauschale 2-Wochen Regel nach PCR ohne Berucksichtigung der Symptomatik einfach umsetzt, und Deutschland das akzeptiert, dann kommen kunftig alle die medizinisch evakuierten COVID-19-Falle, die aus dem Ausland fur ihre Intensivtherapie nach Deutschland gebracht werden, mit gultigem Genesenenzertifikat rein und mussen folglich weder wahrend des Transport noch auf der Intensivstation isoliert werden. Man wird sich allerdings die Frage stellen lassen mussen, warum diese Personen uberhaupt Behandlung brauchen, wo sie doch amtlich genesen sind. Konnte in den Medien etwas schrag ruber kommen.
Habt Ihr Euch das uberlegt?

Viele Gru?e,
Ute Rexroth

Dr. med. Ute Rexroth, MPH MSc

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Council of the European Union

Brussels, 13 April 2021
(OR. en)

7552/21

Interinstitutional Files:
2021/0068(COD)
2021/0071(COD)

LIMITE

COVID-19 122	**COCON 21**
JAI 357	**COMIX 185**
FRONT 120	**CODEC 479**
FREMP 79	**SCHENGEN 23**
IPCR 40	**AVIATION 61**
VISA 67	**PHARM 57**
MI 224	**RELEX 265**
SAN 190	**TOUR 16**
TRANS 191	**POLGEN 47**

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	7128/21 7129/21
Subject:	Digital Green Certificate - Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic - Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable vaccination, testing and recovery certificates for third country nationals legally residing in the Schengen area to facilitate free movement during the COVID-19 pandemic = Mandate for negotiations with the European Parliament

INTRODUCTION

1. On 17 March 2021, the Commission submitted the following proposals:

   – Regulation on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic ("main regulation")[1];

[1] 7128/21

– Regulation on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic ("twin regulation")[2].

Both proposals are subject to the ordinary legislative procedure.

2. On 19 March 2021, Coreper approved the establishment and mandate of the Ad hoc Working Party on the proposals for a Digital Green Certificate (AWP DGC) [3] to examine and negotiate the abovementioned proposals.

3. On 19 and 30 March 2021, Coreper examined the proposals.

4. On 31 March 2021, the European Data Protection Board and the European Data Protection Supervisor issued a joint opinion[4].

5. On 8 and 12 April 2021, the AWP DGC discussed the text of the proposals. The latest version of the proposals can be found in Annexes I and II to this document[5].

STATE OF PLAY

6. Delegations welcomed the proposals which aim to provide a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic.

7. Delegations underlined their commitment to have the framework ready by the summer of 2021. In this context, work would need to advance expeditiously in two parallel tracks: Reaching full agreement on the legislative texts by the beginning of May at the latest and ensuring that the necessary technological solutions are in place in the Member States by the time of the start of operations whilst ensuring coherence with international standards.

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2 7129/21
3 6802/21
4 7307/21
5 Changes compared to the Commission proposal are marked in **bold/underline** for additions and in ~~bold/strikethrough~~ for deletions. New changes compared to the previous version are also grey shaded.

8. As regards the legislative texts, the main amendments which were introduced during the discussions could be summarized as follows:

– In order to stress the principle of non-discrimination, in particular towards non vaccinated persons, the operative part of the main regulation explicitly states that possession of a Digital Green Certificate is no precondition to exercise free movement rights. (Article 3(3a))

– In order to cope with scientific uncertainties, the option has been created for Member States to issue and accept certificates of recovery based on rapid antigen tests, serological testing for antibodies against SARS-CoV-2 or any other scientifically validated method on the basis of future scientific guidance confirming that these tests or methods constitute a reliable proof of recovery. (Article 7(3a) of the main regulation)

– The main regulation includes a justification for the differentiated treatment in the acceptance of vaccination certificates depending on the type of market authorization of the vaccine. (recital 25a and 25b, Article 5(5) and Article 15 (2))

– The text of the main regulation includes a new Article 7a to provide more clarity on the international dimension of the Digital Green Certificate. It clarifies the treatment to be given to certificates issued to Union citizens and their family members as well as legally-staying/residing third-country nationals vaccinated in third countries, both before and after the adequacy finding referred to in paragraph 2 of that article.

– The data protection provisions have been strengthened throughout the text of the main regulation, in particular on the basis of the joint opinion of the European Data Protection Supervisor and the European Data Protection Board (recitals 20a and 47 and Article 9 of the main regulation, recital 18 of the twin regulation)

– The procedure foreseen in Article 10 of the main regulation has been reworded to focus on a timely information exchange between the Member States and the Commission as well as information to the public. As regards the timeline, the same wording as in Recommendation 2020/1475 has been used.

– The Commission proposal made the suspension of the main regulation and the report on its application dependent on non-EU actors. It also provided for the suspension of the main regulation and its possible new application by delegated act. The amended text provides for a 12-month application period, a report by the Commission at the latest 3 months before the end of the application of the main regulation and a possible suspension/extension through the ordinary legislative procedure. (Article 15)

– The text of the main regulation includes a transitional provision to ensure that Member States can continue using the systems that they have currently in place during a short period of six weeks after the entry into force of the main regulation and until the Digital Green Certificate framework is fully operational on their territory (Article 14).

– The text of the main regulation contains amendments in order to limit the scope of the delegated acts aimed at modifying the certificates' data to what is strictly necessary, i.e. scientific progress and interoperability with international standards (Articles 5(2), 6(2) and 7(2)).

– The text of the twin regulation contains a provision enabling Ireland and the other Member States to mutually accept certificates issued to third country nationals based on reciprocity (recital 13 and Article 1a). Furthermore, in this context, small changes were introduced in Article 2 (1) and Article 7a (1) of the main regulation.

CONCLUSION

9. Coreper is invited to examine the text of the two regulations and, on that basis, agree on a mandate for negotiations with the European Parliament.

ANNEX I

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Every citizen of the Union has the **fundamental** right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give effect to them. Directive 2004/38/EC of the European Parliament and of the Council[6] lays down detailed rules as regards the exercise of that right.

(2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (*SARS-CoV-2*), which causes coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.

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[6] Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77).

(3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on citizens' right to move and reside freely within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine/self-isolation or a test for SARS-CoV-2 infection.

(4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic[7]. That Recommendation establishes a coordinated approach on the following key points: the application of common criteria and thresholds when deciding whether to introduce restrictions to free movement, a mapping of the risk of COVID-19 transmission based on an agreed colour code, and a coordinated approach as to the measures, if any, which may appropriately be applied to persons moving between areas, depending on the level of risk of transmission in those areas. In view of their specific situation, the Recommendation also emphasises that essential travellers, as listed in its point 19, and cross-border commuters, whose lives are particularly affected by such restrictions, in particular those exercising critical functions or essential for critical infrastructure, should in principle be exempted from travel restrictions linked to COVID-19.

(5) Using the criteria and thresholds established in Recommendation (EU) 2020/1475, the European Centre for Disease Prevention and Control ('ECDC') has been publishing, once a week, a map of Member States, broken down by regions, in order to support Member States' decision-making[8].

(6) ~~As emphasised by Recommendation (EU) 2020/1475 any,~~ **Member States may limit the fundamental right of free movement for public health reasons. Any** restrictions to the free movement of persons within the Union put in place to limit the spread of COVID-19 should be based on specific and limited public interest grounds, namely the protection of public health **as emphasised by Recommendation (EU) 2020/1475**. It is necessary for such limitations to be applied in compliance with the general principles of Union law, in particular proportionality and non-discrimination. Any measures taken should thus not extend beyond what is strictly necessary to safeguard public health. Furthermore, they should be consistent with measures taken by the Union to ensure seamless free movement of goods and essential services across the Single Market, including those of medical supplies and personnel through the so-called "Green Lane" border crossings referred to in the Commission Communication on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services[9].

(7) The free movement of persons who do not pose a risk to public health, for example because they are immune to and cannot transmit SARS-CoV-2, should not be restricted, as such restrictions would not be necessary to achieve the objective pursued.

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7 OJ L 337, 14.10.2020, p. 3.

8 Available at: https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement

9 OJ C 96I, 24.3.2020, p. 1.

(8) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in a cross-border context when citizens exercise their free movement rights, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.

(9) Unilateral measures in this area have the potential to cause significant disruptions to the exercise of free movement rights, as national authorities and passenger transport services, such as airlines, trains, coaches or ferries, are confronted with a wide array of diverging document formats, not only regarding a person's vaccination status but also on tests and possible recovery from COVID-19.

(10) To facilitate the exercise of the right to move and reside freely within the territory of the Member States, a common framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery, entitled "Digital Green Certificate" should be established.

(11) This Regulation should not be understood as facilitating or encouraging the adoption of restrictions to free movement, or other fundamental rights, in response to the pandemic. In particular, the exemptions to the restriction of free movement in response to the COVID-19 pandemic referred to in Recommendation (EU) 2020/1475 should continue to apply **and the specific situation of cross border communities should be taken into account.** At the same time, the "Digital Green Certificate" framework will ensure that interoperable certificates are also available to essential travellers.

(11a) This Regulation should not cover Member States' decisions to impose or waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19. The use of the Digital Green Certificate in view of lifting restrictions should remain the responsibilty of the Member States.

(12) The foundation of a common approach for the issuance, verification and acceptance of such interoperable certificates hinges upon trust. False COVID-19 certificates may pose a significant risk to public health. Authorities in one Member State need assurance that the information included in a certificate issued in another Member State is trustworthy, that it has not been forged, that it belongs to the person presenting it, and that anyone verifying this information only has access to the minimum amount of information necessary.

(13) The risk posed by false COVID-19 certificates is real. On 1 February 2021, Europol issued an Early Warning Notification on the illicit sales of false negative COVID-19 test certificates[10]. Given the available and easily accessible technological means, such as high-resolution printers and various graphics editor software, fraudsters are able to produce high-quality forged, faked or counterfeit certificates. Cases of illicit sales of fraudulent test certificates have been reported, involving more organised forgery rings and individual opportunistic scammers selling false certificates offline and online.

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10 https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates

(14) To ensure interoperability and equal access, **including for persons with disabilities**, Member States should issue the certificates making up the Digital Green Certificate in a digital or paper-based format, or both, **depending on the choice of the prospective holder**. This should allow the prospective holder to request and receive a paper copy of the certificate or to store and display the certificate on a mobile device. The certificates should contain an interoperable, digitally readable barcode containing the relevant data relating to the certificates. Member States should guarantee the authenticity, validity and integrity of the certificates by electronic seals or similar means. The information on the certificate should also be included in human-readable format, either printed or displayed as plain text. The layout of the certificates should be easy to understand and ensure simplicity and user-friendliness. To avoid obstacles to free movement, **and although there may be a charge for related services, such as for tests**, the certificates **themselves** should be issued free of charge, and citizens should have a right to have them issued. Member States should issue the certificates making up the Digital Green Certificate automatically or upon request, ensuring that they can be obtained easily and providing, where needed, the necessary support to allow for equal access by all citizens.

(15) The security, authenticity, integrity and validity of the certificates making up the Digital Green Certificate and their compliance with Union data protection legislation are key to their acceptance in all Member States. It is therefore necessary to establish a trust framework laying out the rules on and infrastructure for the reliable and secure issuance and verification of certificates. The outline on the interoperability of health certificates[11] adopted, on 12 March 2021, by the eHealth Network set up under Article 14 of Directive 2011/24/EU[12] should form the basis for the trust framework.

(16) Pursuant to this Regulation, the certificates making up the Digital Green Certificate should be issued to beneficiaries as referred to in Article 3 of Directive 2004/38/EC, that is, Union citizens and their family members, by the Member State of vaccination or test, or where the recovered person is located. **Where reference is made to issuance by Member States, this should be understood as also covering issuance by designated bodies on behalf of Member States, including when they are issued in Overseas Countries and Territories or the Faroe Islands on behalf of a Member State.** Where relevant or appropriate, the certificates should be issued on behalf of the vaccinated, tested or recovered person, for example on behalf of legally incapacitated persons or to parents on behalf of their children. The certificates should not require legalisation or other similar formalities.

(17) The certificates making up the Digital Green Certificate could also be issued to nationals or residents of Andorra, Monaco, San Marino and the Vatican/Holy See. ~~in particular where they are vaccinated by a Member State.~~

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[11] Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf

[12] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

(18) It is necessary to take into account that the agreements on free movement of persons concluded by the Union and its Member States, of the one part, and certain third countries, of the other part, provide for the possibility to restrict free movement for public health reasons. Where such an agreement does not contain a mechanism of incorporation of European Union acts, certificates issued to beneficiaries of such agreements should be accepted under the conditions laid down in this Regulation. This should be conditional on an implementing act to be adopted by the Commission establishing that such a third country issues certificates in accordance with this Regulation and has provided formal assurances that it would accept certificates issued by the Member States.

(19) Regulation (EU) 2021/XXXX applies to third-country nationals who do not fall within the scope of this Regulation and who reside or stay legally in the territory of a State to which that Regulation applies and who are entitled to travel to other States in accordance with Union law.

(20) The framework to be established for the purpose of this Regulation should seek to ensure coherence with global initiatives, in particular involving the WHO **and the International Civil Aviation Organisation (ICAO)**. This should include, where possible, interoperability between technological systems established at global level and the systems established for the purpose of this Regulation to facilitate free movement within the Union, including through the participation in a public key infrastructure or the bilateral exchange of public keys. To facilitate the free movement rights of Union citizens vaccinated **or tested** by third countries **or by Overseas Countries or Territories referred to in Article 355 (2) TFEU or listed in its annex II or the Faroe Islands**, this Regulation should provide for the acceptance of certificates issued by third countries **or by Overseas Countries or Territories or the Faroe Islands** to Union citizens and their family members where the Commission finds that these certificates are issued according to standards equivalent to those established pursuant to this Regulation.

(20a) If the technical solution chosen for verification requires a Member State to transfer personal data to a recipient in a third country to confirm and verify the vaccination, testing or recovery status of the holder of a certificate issued by a third country, such transfer should be limited to the data necessary for the verification of the authenticity, validity and integrity of the certificate and may only be carried out in compliance with the conditions set out in Chapter V of Regulation (EU) 2016/679.

(21) To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable vaccination certificate should be established. This vaccination certificate should serve to confirm that the holder has received a COVID-19 vaccine in a Member State. The certificate should contain only the necessary information to clearly identify the holder as well as the COVID-19 vaccine, number, date and place of vaccination. Member States should issue vaccination certificates **to** ~~for~~ persons receiving vaccines that have been granted marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council[13], ~~for~~ vaccines that have been granted marketing authorisation pursuant to Directive 2001/83/EC of the European Parliament and of the Council[14], or vaccines whose distribution has been temporarily authorised pursuant to Article 5(2) of Directive 2001/83/EC.

(22) Persons who have been vaccinated before the date of application of this Regulation, including as part of a clinical trial, should also have the **right** ~~possibility~~ to obtain a certificate on COVID-19 vaccination that complies with this Regulation **given that the Digital Green Certificate provides the mutually accepted framework to facilitate free movement**. **Where Union citizens or their family members are not in possession of a certificate that complies with the requirements of this Regulation, in particular because they have been vaccinated before the entry into force of this Regulation, they should be given every reasonable opportunity to corroborate or prove by other means that they should benefit from the waiving of relevant restrictions to free movement afforded by a Member State. This should not be understood as affecting the obligation of Member States to issue certificates that comply with the requirements of this Regulation nor the right of Union citizens or their family members to receive, from Member States, certificates that comply with the requirements of this Regulation.** At the same time, Member States should remain free to issue proofs of vaccination in other formats for other purposes, in particular for medical purposes.

(23) Member States **may** also issue **upon request** such vaccination certificates to Union citizens and their family members who have been vaccinated in a third country and provide **all necessary information, including** reliable proof to that effect. **This is of particular importance to allow the persons concerned to make use of an interoperable and accepted vaccination certificate when exercising their right of free movement within the Union. There is no requirement for Member States to issue such vaccination certificates at consular posts.**

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13 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

14 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67).

(24) On 27 January 2021, the eHealth Network adopted guidelines on proof of vaccination for medical purposes, which it updated on 12 March 2021[15]. These guidelines, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.

(25) Already now, several Member States exempt vaccinated persons from certain restrictions to free movement within the Union. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation. This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers sufficient a single dose of a vaccine administered, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. ~~On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing.~~

[15] Available at : https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

(25a) Regulation (EC) No 726/2004 puts in place harmonised procedures, involving all Member States, for the authorisation and surveillance of medicinal products at Union level, ensuring that only high quality medicinal products are placed on the market and administered to persons throughout the Union. As a result, the marketing authorisations granted by the Union pursuant to Regulation (EC) No 726/2004, including the underlying evaluation of the medicinal product concerned in terms of quality, safety and efficacy, are valid in all Member States. In addition, efficacy follow-up and supervision procedures of medicinal products authorised pursuant to Regulation (EC) No 726/2004 are carried out centrally for all Member States. The assessment and approval of vaccines via the centralised procedure follows shared standards and is done in a consistent way on behalf of all Member States. Member States' participation in the review and endorsement of the assessment is ensured through various committees and groups, which also benefits from the expertise from the EU Medicines Regulatory Network. The authorisation via the centralised procedure provides the confidence that all Member States can rely on the authorisation and data on efficacy as well as safety and on the consistency of the batches being used for vaccination of citizens. The obligation to accept, under the same conditions, valid vaccination certificates issued by other Member States should therefore cover COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. In order to support the work of WHO and to strive for better global interoperability, Member States are in particular encouraged to accept vaccination certificates issued for other COVID-19 vaccines having received a WHO Emergency Use Listing.

(25b) This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing. Where one of these COVID-19 vaccines is subsequently granted marketing authorisation pursuant to Regulation (EC) No 726/2004, the obligation to accept, under the same conditions, would also cover valid vaccination certificates issued by a Member States for that COVID-19 vaccine, regardless whether the certificates were issued before or after the authorisation via the centralised procedure.

(26) It is necessary to prevent discrimination against persons who are not vaccinated, for example because of medical reasons, because they are not part of the target group for which the vaccine is currently recommended **or allowed, such as children**, or because they have not yet had the opportunity or chose not to be vaccinated. Therefore, possession of a vaccination certificate, or the possession of a vaccination certificate indicating a specific vaccine medicinal product, should not be a pre-condition to exercise free movement rights, in particular where those persons are, by other means, able to show compliance with lawful, public-health-related requirements, and cannot be a pre-condition to use cross-border passenger transport services such as airlines, trains, coaches or ferries.

(27) Many Member States have been requiring persons travelling to their territory to undergo a test for SARS-CoV-2 infection before or after arrival. At the beginning of the COVID-19 pandemic, Member States typically relied on reverse transcription polymerase chain reaction (RT-PCR), which is a nucleic acid amplification test (NAAT) for COVID-19 diagnostics considered by the WHO and ECDC as the 'gold standard', that is, the most reliable methodology for testing of cases and contacts[16]. As the pandemic has progressed, a new generation of faster and cheaper tests has become available on the European market, the so-called rapid antigen tests, which detect the presence of viral proteins (antigens) to detect an ongoing infection. On 18 November 2020, the Commission adopted Commission Recommendation (EU) 2020/1743 on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection[17].

(28) On 22 January 2021, the Council adopted Council Recommendation 2021/C 24/01 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU[18], which provides for the development of a common list of COVID-19 rapid antigen tests. On this basis, the Health Security Committee agreed, on 18 February 2021, on a common list of COVID-19 rapid antigen tests, a selection of rapid antigen tests for which Member States will mutually recognise their results, and a common standardised set of data to be included in COVID-19 test result certificates[19].

(29) Despite these common efforts, Union citizens and their family members exercising their free movement right still face problems when trying to use a test result obtained in one Member State in another. These problems are often linked to the language in which the test result is issued, or to lack of trust in the authenticity of the document shown. **Such problems are compounded for persons who cannot be vaccinated yet, in particular children, for whom test results may be the only way to travel in case restrictions are in place.**

(30) To improve the acceptance of test results carried out in another Member State when presenting such results for the purposes of exercising free movement, an interoperable test certificate should be established, containing the necessary information to clearly identify the holder as well as the type, date and result of the test for SARS-CoV-2 infection. To ensure the reliability of the test result, only the results of NAAT tests and rapid antigen tests featured in the list established on the basis of Council Recommendation 2021/C 24/01 should be eligible for a test certificate issued on the basis of this Regulation. The common standardised set of data to be included in COVID-19 test result certificates agreed by the Health Security Committee on the basis of Council Recommendation 2021/C 24/01, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.

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16 https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf

17 OJ L 392, 23.11.2020, p. 63.

18 OJ C 24, 22.1.2021, p. 1.

19 https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf

(31) Test certificates issued by Member States in compliance with this Regulation should be accepted by Member States requiring proof of a test for SARS-CoV-2 infection in the context of the restrictions to free movement put in place to limit the spread of COVID-19.

(32) According to existing evidence, persons who have recovered from COVID-19 can continue to test positive for SARS-CoV-2 for a certain period after symptom onset[20]. Where such persons are required to undergo a test when seeking to exercise free movement, they may thus be effectively prevented from travelling despite no longer being infectious. To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable certificate of recovery should be established, containing the necessary information to clearly identify the person concerned and the date of a previous positive test for SARS-CoV-2 infection. A certificate of recovery should be issued at the earliest from the eleventh day after the first positive test and should be valid for not more than 180 days. According to ECDC, recent evidence shows that despite shedding of viable SARS-CoV-2 between ten and twenty days from the onset of symptoms, convincing epidemiological studies have failed to show onward transmission of disease after day ten. The Commission should be empowered to change this period on the basis of guidance from the Health Security Committee or from ECDC, which is closely studying the evidence base for the duration of acquired immunity after recovery.

(33) Already now, several Member States exempt recovered persons from certain restrictions to free movement within the Union. Where Member States accept proof of recovery in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of SARS-CoV-2, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation. The eHealth Network, in collaboration with Health Security Committee, is also working on guidelines on recovery certificates and respective datasets.

(33a) Taking into account the latest scientific and technological developments, the Commission should be empowered to adapt the provisions on the certificate of recovery by providing for its issuance on the basis of a positive rapid antigen test, serological testing for antibodies against SARS-CoV-2 or any other scientifically reliable method by means of a delegated act. This delegated act should include the necessary data fields on the categories of data to be included in the certificate. It should also contain specific provisions on the maximum validity period as it might depend on the type of the test carried out. The issuance and acceptance of the certificate of recovery based on the tests and methods mentioned above should be optional.

[20] https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-ending-of-isolation-of-people-with-COVID-19.pdf

(34) To be able to obtain a common position quickly, the Commission should be able to ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council[21] to issue guidance about the available scientific evidence concerning the effects of medical events documented in the certificates established in accordance with this Regulation, including the effectiveness and duration of the immunity conferred by COVID-19 vaccines, whether vaccines prevent asymptomatic infection and transmission of the virus, the situation of people having recovered from the virus, and the impacts of the new SARS-CoV-2 variants on people having been vaccinated or already contaminated.

(35) In order to ensure uniform conditions for the implementation of the trust framework certificates established by this Regulation, implementing powers should be conferred on the Commission. Those powers should be *exercised* in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[22].

(36) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the technical specifications necessary to establish interoperable certificates*,* imperative grounds of urgency so require or when new scientific evidence becomes available.

(37) Regulation (EU) 2016/679 of the European Parliament and of the Council[23] applies to the processing of personal data carried out when implementing this Regulation. This Regulation establishes the legal ground for the processing of personal data, within the meaning of Articles 6(1)(c) and 9(2)(g) of Regulation (EU) 2016/679, necessary for the issuance and verification of the interoperable certificates provided for in this Regulation. It ~~also~~ does not regulate the processing of personal data related to the documentation of a vaccination, test or recovery event for other purposes, such as for the purposes of pharmacovigilance or for the maintenance of individual personal health records. **Member States may process such data for other purposes, if** ~~T~~the legal basis for processing **of such data** for other purposes, **including the related retention periods,** is ~~to be~~ provided for in national law, which must comply with Union data protection legislation.

(38) In line with the principle of minimisation of personal data, the certificates should only contain the personal data necessary for the purpose of facilitating the exercise of the right to free movement within the Union during the COVID-19 pandemic. The specific categories of personal data and data fields to be included in the certificates should be set out in this Regulation.

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21 Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

22 OJ L 55, 28.2.2011, p. 13.

23 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

(39) For the purposes of this Regulation, personal data may be transmitted/exchanged across borders with the sole purpose of obtaining the information necessary to confirm and verify the holder's vaccination, testing or recovery status. In particular, it should allow for the verification of the authenticity of the certificate.

(40) This Regulation does not create a legal basis for retaining personal data obtained from the certificate by the Member State of destination or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic.

(41) To ensure coordination, the Member States and the Commission should be informed when a Member State requires holders of certificates to undergo, after entry into its territory, quarantine/self-isolation or a test for SARS-CoV-2 infection, or if it **imposes other restrictions on holders of such certificates** ~~denies entry to such persons~~.

(41a) Clear, comprehensive and timely communication to the public on the issuance and acceptance of each type of certificate making up the Digital Green Certificate is crucial to ensure predictability for travel and legal certainty. The Commission should support the Member States' efforts in this regard, for example by making available the information provided by Member States on the 'Re-open EU' web platform.

(42) In accordance with Recommendation (EU) 2020/1475, any restrictions to the free movement of persons within the Union put in place to limit the spread of SARS-CoV-2 should be lifted as soon as the epidemiological situation allows. This also applies to obligations to present documents other than those required by Union law, in particular Directive 2004/38/EC, such as the certificates covered by this Regulation. ~~Therefore, the Regulation's provisions on the "Digital Green Certificate" framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery should be suspended once the Director-General of the WHO has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended. At the same time, their application should resume if the Director-General of the WHO declares another public health emergency of international concern due to an outbreak of SARS-CoV-2, a variant thereof, or similar infectious diseases with epidemic potential. Where this is the case, the provisions concerned should again be suspended once that public health emergency of international concern has ended.~~**This Regulation should apply for 12 months from the date of its entry into force.** ~~(43)~~ **At the latest 3 months before the end of the application of this Regulation, taking into account the evolution of the epidemiological situation on the pandemic,** the Commission should publish a report on the lessons learned from the application of this Regulation, including on its impact on the facilitation of free movement and data protection. ~~one year after the Director-General of the WHO has declared that the public health emergency of international concern caused by SARS-CoV-2 has ended~~.

(42a) A transitional period should be provided to give Member States the possibility to continue issuing certificates which are not yet in compliance with this Regulation. During the transitional period, such certificates as well as certificates issued before the entry into force of this Regulation should be accepted by Member States provided they contain the necessary data.

(44) In order to take into account the epidemiological situation and the progress in containing the COVID-19 pandemic and to ensure interoperability with international standards, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the application of certain Articles of this Regulation as well as the list of personal data to be included in the certificates covered by this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[24]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(45) Since the objectives of this Regulation, namely to facilitate the free movement within the Union during the COVID-19 pandemic by establishing interoperable certificates on the holder's vaccination, testing and recovery status, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(46) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights ('Charter'), including the right to respect for private life and family life, the right to the protection of personal data, the right to equality before the law and non-discrimination, the right to free movement and the right to an effective remedy. Member States should comply with the Charter when implementing this Regulation.

(47) The European Data Protection Supervisor **and the European Data Protection Board have** ~~has~~ been consulted ~~pursuant to~~ in accordance with Article 42~~(1)~~ of Regulation (EU) 2018/1725[25] **and delivered a joint opinion on 31 March 2021**,

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[24] OJ L 123, 12.5.2016, p. 1.

[25] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

HAVE ADOPTED THIS REGULATION:

Article 1
Subject matter

This Regulation lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery. **It shall** ~~in order to~~ facilitate the holders' exercise of their right to free movement during the COVID-19 pandemic ("Digital Green Certificate").

It provides for the legal ground to process personal data necessary to issue such certificates and to process the information necessary to confirm and verify the authenticity and validity of such certificates.

Article 2
Definitions

For the purposes of this Regulation, the following definitions apply:

(1) "holder" means the **person** ~~Union citizen or their family members~~ to whom an interoperable certificate containing information about his or her vaccination, testing and/or recovery status has been issued in accordance with this Regulation.

(2) "Digital Green Certificate" means interoperable certificates containing information about the vaccination, testing and/or recovery status of the holder issued in the context of the COVID-19 pandemic;

(3) "COVID-19 vaccine" means an immunological medicinal product indicated for active immunisation to prevent COVID-19;

(4) "NAAT test" means a molecular nucleic acid amplification test (NAAT), such as reverse transcription polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques, used to detect the presence of the SARS-CoV-2 ribonucleic acid (RNA);

(5) "rapid antigen test" means a testing method that relies on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes;

(6) "interoperability" means the capability of verifying systems in a Member State to use data encoded by another Member State;

(7) "barcode" means a method of storing and representing data in a visual, machine-readable format;

(8) "electronic seal" means data in electronic form, which is attached to or logically associated with other data in electronic form to ensure the latter's origin and integrity;

(9) "unique certificate identifier" means a unique identifier given, in accordance with a common structure, to each certificate issued in accordance with this Regulation;

(10) "trust framework" means the rules, policies, specifications, protocols, data formats and digital infrastructure regulating and allowing for the reliable and secure issuance and verification of certificates to guarantee the certificates' trustworthiness by confirming their authenticity, validity and integrity, including by the possible use of electronic seals.

Article 3
Digital Green Certificate

1. The interoperable Digital Green Certificate **framework** shall allow for the issuance and cross-border verification and acceptance of any of the following certificates:

   (a) a certificate confirming that the holder has received a COVID-19 vaccine in the Member State issuing the certificate ('vaccination certificate');

   (b) a certificate indicating the holder's result**, type** and date of a NAAT test or a rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01[26] **carried out by health professionals in the Member State issuing the certificate** ('test certificate');

   (c) a certificate confirming that the holder has recovered from a SARS-CoV-2 infection following a positive NAAT test ~~or a positive rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Recommendation 2021/C 24/01~~ ('certificate of recovery').

   The Commission shall publish the list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01, including any updates.

2. Member States, **or designated bodies acting on behalf of Member States,** shall issue the certificates referred to in paragraph 1 in a digital or paper-based format, or both. The certificates issued by Member States shall contain an interoperable barcode allowing for the verification of the authenticity, validity and integrity of the certificate. The barcode shall comply with the technical specifications established in accordance with Article 8. The information contained in the certificates shall also be shown in human-readable form and shall be, at least, in the official language or languages of the issuing Member State and English.

[26] Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (2021/C 24/01) (OJ C 24, 22.1.2021, p. 1).

3. The certificates referred to in paragraph 1 shall be issued free of charge. The holder shall be entitled to request the issuance of a new certificate if the personal data contained in the certificate is not or no longer accurate or up to date, or the certificate is no longer available to the holder. **Appropriate fees may be charged in case of repeated loss.**

3a The certificate shall include the following text:

"This certificate is not a travel document. The scientific evidence on COVID-19 vaccination, testing and recovery continues to evolve, also in view of new variants of concern of the virus. Before traveling, please check the applicable public health measures and related restrictions applied at the point of destination."

3b Possession of a Digital Green Certificate shall not be a precondition to exercise free movement rights.

4. Issuance of the certificates referred to in paragraph 1 shall not affect the validity of other proofs of vaccination, test or recovery issued before the entry into application of this Regulation or for other purposes, in particular for medical purposes.

5. Where the Commission has adopted an implementing act pursuant to the second sub-paragraph, certificates **equivalent to those** issued in accordance with this Regulation by a third country with which the European Union and its Member States have concluded an agreement on free movement of persons allowing the contracting parties to restrict such free movement on grounds of public health in a non-discriminatory manner and which does not contain a mechanism of incorporation of European Union acts shall be accepted under the conditions referred to in Articles 5(5), **6(5) and 7(5)**.

The Commission shall assess whether such a third country issues certificates **equivalent to those issued** in accordance with this Regulation and has provided formal assurances that it will accept certificates issued by the Member States. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).

6. **Where necessary,** the Commission **shall** ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU**, the European Center for Disease Prevention and Control or the European Medicines Agency** to issue guidance on the available scientific evidence on the effects of medical events documented in the certificates referred to in paragraph 1, **in particular in view of newly emerging SARS-CoV-2 variants of concern**.

Article 4
Digital Green Certificate trust framework

1. The Commission and the Member States shall set up and maintain a trust framework digital infrastructure allowing for the secure issuance and verification of the certificates referred to in Article 3.

2. The trust framework shall **seek to** ensure~~, where possible,~~ interoperability with technological systems established at international level.

~~3. Where the Commission has adopted an implementing act pursuant to the second sub-paragraph, certificates issued by third countries to Union citizens and their family members according to an international standard and technological system that are interoperable with the trust framework established on the basis of this Regulation and that allows for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union. For the purposes of this sub-paragraph, the acceptance, by the Member States, of vaccination certificates issued by third countries shall take place under the conditions referred to in Article 5(5).~~

~~The Commission shall assess whether certificates issued by a third country fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).~~

Article 5
Vaccination certificate

1. Each Member State shall issue vaccination certificates as referred to in Article 3(1)(a) to a person to whom a COVID-19 vaccine has been administered, either automatically or upon request by that person.

2. The vaccination certificate shall contain the following categories of ~~personal~~ data:

   (a) identification of the holder;

   (b) information about the vaccine medicinal product administered;

   (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

   The ~~personal~~ data shall be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 1 of the Annex by adding, modifying or removing data fields, ~~on the categories of personal data mentioned in this paragraph~~ **where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate, in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.**

3. The vaccination certificate shall be issued in a secure and interoperable format as provided for in Article 3(2) **after the administration of each dose** and shall clearly indicate whether or not the vaccination course has been completed.

4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.

5. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall also accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004.

Member States may also accept, for the same purpose, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, a COVID-19 vaccine whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or a COVID-19 vaccine having received a WHO Emergency Use Listing. **Where Member States accept valid vaccination certificates issued in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, a COVID-19 vaccine whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or a COVID-19 vaccine having received a WHO Emergency Use Listing they shall also accept, under the same conditions, valid vaccination certificates issued by other Member States.**

~~6. Where a Union citizen or a family member of a Union citizen has been vaccinated in a third country with one of the types of COVID-19 vaccines referred to in paragraph 5 of this Article, and where the authorities of a Member State have been provided with all necessary information, including reliable proof of vaccination, they shall issue a vaccination certificate as referred to in Article 3(1)(a) to the person concerned.~~

Article 6
Test certificate

1. Each Member State shall issue test certificates as referred to in Article 3(1)(b) to persons tested for COVID-19, either automatically or upon request by that person.

2. The test certificate shall contain the following categories of ~~personal~~ data:

   (a) identification of the holder;

   (b) information about the test carried out;

   (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

   The ~~personal~~ data shall be included in the test certificate in accordance with the specific data fields set out in point 2 of the Annex.

   The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 2 of the Annex by adding, modifying or removing data fields ~~on the categories of personal data mentioned in this paragraph~~ **where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate, in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.**

3. The test certificate shall be issued in a secure and interoperable format as provided for in Article 3(2).

4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.

5. Where Member States require proof of a test for SARS-CoV-2 infection as part of the restrictions to free movement put in place, in compliance with Union law **and taking into account the specific situation of cross-border communities**, to limit the spread of COVID-19, they shall also accept**, under the same conditions,** valid test certificates issued by other Member States in compliance with this Regulation.

Article 7
Certificate of recovery

1. Each Member State shall issue, upon request, certificates of recovery as referred to in Article 3(1)(c) at the earliest from the eleventh day after a person has received his or her first positive test for SARS-CoV-2 infection.

   The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the number of days as of which a certificate of recovery may be issued, based on guidance received from the Health Security Committee in accordance with Article 3(6) or on scientific evidence reviewed by ECDC.

2. The certificate of recovery shall contain the following categories of ~~personal~~ data:

(a) identification of the holder;

(b) information about past SARS-CoV-2 infection **following a positive test**;

(c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

The ~~personal~~ data shall be included in the certificate of recovery in accordance with the specific data fields set out in point 3 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 3 of the Annex by adding, modifying or removing data fields ~~on the categories of personal data mentioned in this paragraph~~, including until when a certificate of recovery shall be valid, **where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate, in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.**

3. The certificate of recovery shall be issued in a secure and interoperable format as provided for in Article 3(2).

3a Based on guidance received pursuant to Article 3(6), the Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the provisions in Article 3(1)(c) and Article 7(1) to allow for the issuance of the certificate of recovery also based on a positive rapid antigen test, serological testing for antibodies against SARS-CoV-2 or any other scientifically validated method. Any such delegated act shall add, modify or remove the data fields on the categories of data included in the certificate. The issuance and acceptance of the certificate of recovery based on the tests and methods mentioned in this paragraph shall be optional.

4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.

5. Where Member States accept proof of recovery from SARS-CoV-2 infection as a basis for waiving restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation.

New Article 7a

COVID-19 certificates and other documentation issued by a third country

1. **Where a vaccination certificate has been issued in a third country for a vaccine medicinal product that corresponds to one of the COVID-19 vaccines referred to Article 5(5) and where the authorities in a Member State have been provided with all necessary information, including reliable proof of vaccination, they may, upon request, issue a vaccination certificate as referred to in Article 3(1)(a) to the person concerned. A Member State shall not be required to issue a certificate for a vaccine not authorised for use on its territory.**

2. **Where the Commission has adopted an implementing act pursuant to the second sub-paragraph, certificates referred to in Article 3 issued by third countries according to a standard and technological system that are interoperable with the trust framework established on the basis of this Regulation that allow for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union.**

The Commission shall assess whether certificates issued by a third country fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).

3. **For the purposes of this article, the acceptance by the Member States of certificates issued pursuant to this Article, shall take place under the conditions referred to in Articles 5(5), 6(5) and 7(5).**

4. **If a Member State accepts a certificate for a COVID-19 vaccine referred to in Article 5(5) second subparagraph issued pursuant to this Article, it shall also accept certificates for the same COVID-19 vaccine issued by a Member State.**

4a. **This Article shall also apply to COVID-19 certificates and other documentation issued by Overseas Countries and Territories referred to in Article 355(2) TFEU and listed in its Annex II, and by the Faroe Islands. It shall not apply to COVID-19 certificates and other documentation issued in Overseas Countries and Territories referred to in Article 355(2) TFEU and listed in its Annex II, and in the Faroe Islands, issued on behalf of a Member State.**

Article 8
Technical specifications

To ensure uniform conditions for implementation of the trust framework established by this Regulation, the Commission shall adopt implementing acts containing the technical specifications and rules to:

(a) securely issue and verify the certificates referred to Article 3;

(b) ensure the security of the personal data, taking into account the nature of the data;

(c) populate the certificates referred to Article 3, including the coding system and any other relevant elements;

(d) lay down the common structure of the unique certificate identifier;

(e) issue a valid, secure and interoperable barcode;

(f) ensure**, where possible,** interoperability with international standards and/or technological systems;

(g) allocate responsibilities amongst controllers and as regards processors, **in accordance with Article 28(3) of Regulation 2016/679**.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(2).

On duly justified imperative grounds of urgency, in particular to ensure a timely implementation of the trust framework, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 13(3).

Article 9
Protection of personal data

0. **Regulation (EU) 2016/679 shall apply to the processing of personal data carried out when implementing this Regulation.**

1. The personal data contained in the certificates issued in accordance with this Regulation shall be processed **only** for the purpose of accessing and verifying the information included in the certificate in order to facilitate the exercise of the right of free movement within the Union during the COVID-19 pandemic.

2. The personal data included in the certificates referred to in Article 3 shall be processed by the competent authorities of the Member State of destination **or transit**, or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic, to confirm and verify the holder's vaccination, testing or recovery status. For this purpose, the personal data shall be limited to what is strictly necessary. The personal data accessed pursuant to this paragraph shall not be retained.

3. The personal data processed for the purpose of issuing the certificates referred to in Article 3, including the issuance of a new certificate, shall not be retained longer than is necessary for its purpose and in no case longer than the period for which the certificates may be used to exercise the right to free movement.

4. The authorities **or other designated bodies** responsible for issuing the certificates referred to in Article 3 shall be considered as controllers referred to in Article 4(7) of Regulation (EU) 2016/679.

4a. The natural or legal person, public authority, agency or other body that has administered the vaccine or carried out the test for which a certificate is to be issued shall transmit to the authorities or other designated bodies responsible for issuing the certificates the categories of data referred to in Articles 5(2), 6(2) and 7(2) necessary to complete the data fields set out in the Annex.

Article 10

Information exchange *~~Notification procedure~~*

1. Member States shall **inform other** ~~notify~~ Member States and the Commission on the **issuance and** acceptance of the certificates referred to in Article 3 and the conditions thereof, **including which vaccines they accept pursuant to Article 5(5) second subparagraph**.

2. Where a Member State requires holders of certificates referred to in Article 3 to undergo, after entry into its territory, quarantine, self-isolation or a test for SARS-CoV-2 infection, or if it **imposes other restrictions on holders of such certificates** ~~denies entry to such persons~~, it shall **inform,** ~~notify~~ the other Member States and the Commission **thereof, if possible 48 hours in advance of the introduction of new measures.** ~~before the planned introduction of such restrictions.~~ To that end, the Member State shall supply the following information:

   (a) the reasons for such restrictions ~~including all relevant epidemiological data supporting such restrictions~~;

   (b) the scope of such restrictions, specifying **the holders of which certificates** ~~which travellers~~ are subject to or exempt from such restrictions;

   (c) the date and duration of the restrictions.

   ~~Where necessary, the Commission may request additional information from the Member State concerned.~~

2a Member States shall provide the public with clear, comprehensive and timely information on the topics covered by paragraphs 1 and 2. As a general rule, this information should be published 24 hours before the measures come into effect, taking into account that some flexibility is required for epidemiological emergences. The information provided by the Member States may also be made publicly available by the Commission in a centralised manner.

Article 11
Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 5(2), 6(2), 7(1) **and** ~~,~~ 7(2) ~~and 15~~ shall be conferred on the Commission for an indeterminate period of time from [date of entry into force].

3. The delegation of power referred to in Articles 5(2), 6(2), 7(1) **and** ~~,~~ 7(2) ~~and 15~~ may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 5(2), 6(2), 7(1) **and** ~~,~~ 7(2) ~~and 15~~ shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 12
Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 11(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Article 13
Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 14
Transitional provision

Member States may issue the certificates referred to in Article 3 in a format which does not comply with the requirements of this Regulation until 6 weeks after the entry into force of this Regulation. During this period, certificates issued in accordance with this Article as well as certificates issued before the entry of force of this Regulation shall be accepted by the Member States in accordance with Articles 5(5), 6(5) and 7(5) where they contain the data fields set out in the Annex.

~~*Reporting*~~

~~One year after the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation.~~

~~The report shall contain, in particular, an assessment of the impact of this Regulation on the facilitation of free movement of Union citizens and their family members as well as on the protection of personal data during the COVID-19 pandemic.~~

Article 15
*Entry into force, applicability **and reporting***

1. This Regulation shall enter into force on**, and apply from,** the ~~third~~ day ~~following that~~ of its publication in the *Official Journal of the European Union*.

2. **The Regulation shall apply for 12 months from the date of its entry into force.**

At the latest 3 months before the end of the application of this Regulation, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation.

The report shall contain, in particular, an assessment of the impact of this Regulation on the facilitation of free movement, including the acceptance of the different types of vaccines, as well as on the protection of personal data during the COVID-19 pandemic.

This report may be accompanied with legislative proposals, in particular to extend the date of application of this Regulation, taking into account the evolution of the epidemiological situation on the pandemic.

~~2. The Commission shall adopt a delegated act in accordance with Article 11 specifying the date from which the application of Articles 3, 4, 5, 6, 7 and 10 is to be suspended once the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended.~~

~~*3.* The Commission is empowered to adopt a delegated act in accordance with Article 11 specifying the date from which Articles 3, 4, 5, 6, 7 and 10 are to apply again if, after the suspension referred to in paragraph 2 of this Article, the Director-General of the World Health Organization declares a public health emergency of international concern in relation to *SARS-CoV-2, a variant thereof, or similar* infectious diseases with epidemic potential. *Following the adoption of such a delegated act, paragraph 2 of this Article shall apply.*~~

~~4. Where, in the case of developments regarding public health emergencies of international concern, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.~~

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX
Certificate datasets

Data fields to be included in the vaccination certificate:

(a) name: surname(s) and forename(s), in that order;

(b) date of birth;

(c) disease or agent targeted: **COVID-19**;

(d) vaccine/prophylaxis;

(e) vaccine medicinal product;

(f) vaccine marketing authorization holder or manufacturer;

(g) number in a series of vaccinations/doses **and the overall number of doses in the series**;

(h) date of vaccination, indicating the date of the latest dose received;

(i) Member State of vaccination;

(j) certificate issuer;

(k) a unique certificate identifier.

Data fields to be included in the test certificate:

(a) name: surname(s) and forename(s), in that order;

(b) date of birth;

(c) disease or agent targeted: **COVID-19**;

(d) the type of test;

(e) test name (optional for NAAT test);

(f) test manufacturer (optional for NAAT test);

(g) date and time of the test sample collection;

(h) date and time of the test result production (optional for rapid antigen test);

(i) result of the test;

(j) testing centre or facility;

(k) Member State of test;

(l) certificate issuer;

(m) a unique certificate identifier.

Data fields to be included in the certificate of recovery:

(a) name: surname(s) and forename(s), in that order;

(b) date of birth;

(c) disease or agent the citizen has recovered from: **COVID-19**;

(d) date of first positive test result;

(e) Member State of test;

(f) certificate issuer;

(g) certificate valid from;

(h) certificate valid until (not more than 180 days after the date of first positive test result);

(i) a unique certificate identifier.

ANNEX II

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic (Digital Green Certificate)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 77(2)(c)thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Under the Schengen acquis, third country nationals lawfully residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the territories of all other Member States during a period of 90 days in any 180-day period.

(2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (*SARS-CoV-2*), which causes coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.

(3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on travel to and within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine.

(4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic[1].

(5) On 30 October 2020, the Council adopted Council Recommendation (EU) 2020/1632[2] on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area, in which it recommended Member States that are bound by the Schengen *acquis* to apply the principles, common criteria, common thresholds and common framework of measures, set out in Council Recommendation (EU) 2020/1475.

(6) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in connection with cross-border travel within the Union, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.

(7) Already now, several Member States exempt vaccinated persons from certain travel restrictions. Where Member States accept proof of vaccination in order to waive travel restrictions put in place in compliance with Union law to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with the proposal for a Regulation on a Digital Green Certificate (COM(2021)/xxx). This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers a single dose of an administered vaccine to be sufficient, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council[3]. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC of the European Parliament and the Council[4], vaccines whose distribution has been temporarily authorised based on Article 5(2) of that Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing. Regulation (EU) No 2021/xxxx of xx xx 2021 lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic. It applies to Union citizens and third-country nationals who are family members of Union citizens.

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1 OJ L 337, 14.10.2020, p. 3.

2 Council Recommendation (EU) 2020/1632 of 30 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area (OJ L 366, 4.11.2020, p. 25).

3 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p.1).

4 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(8) In accordance with Articles 19, 20 and 21 of the Convention implementing the Schengen Agreement, the third-country nationals covered by these provisions may travel freely within the territories of the other Member States.

(9) To facilitate travel within the territories of the Member States by third country nationals who have the right to such travel, the framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery established by Regulation (EU) No 2021/xxxx should also apply to third-country nationals who are not already covered by that Regulation, provided that they are legally staying or legally residing in the territory of a Member State and are entitled to travel to other Member States in accordance with Union law.

(10) For certificates to be used effectively in connection with cross-border travel, such certificates need to be fully interoperable.

(11) This Regulation should not be understood as facilitating or encouraging the adoption of travel restrictions to free movement, or other fundamental rights, in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/xxx cannot as such justify the temporary reintroduction of border controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules set out in Regulation (EU) 2016/399 (Schengen Borders Code)[5].

(11a) Since this Regulation applies to third country nationals already legally staying or residing in the territories of the Member States, it should not be understood as granting third country nationals wishing to travel to a Member State the right to request a Digital Green Certificate from that Member State before arrival on its territory.

(11b) On 30 June 2020, the Council adopted Recommendation (EU) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction. This Regulation does not cover the temporary restrictions on non-essential travel into the Union.

(12) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen acquis, Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it.

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[5] Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (OJ L 77, 23.3.2016 p.1).

(13) This Regulation constitutes a development of the provisions of the Schengen acquis in which Ireland does not take part, in accordance with Council Decision 2002/192/EC[6]; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application. **In order to allow Member States to accept, under the conditions of the Regulation (EU) 2021/XXXX [Regulation on a Digital Green Certificate], certificates issued by Ireland to third country nationals legally residing or legally staying in its territory for the purposes of facilitating travel within the Union, Ireland should issue these third-country nationals with certificates that comply with the requirements of the Digital Green Certificate trust framework.** ~~Although Ireland is not subject to this Regulation, for the purposes of facilitating travel within the Union, Ireland could also issue certificates, which comply with the same requirements as those applicable to the Digital Green Certificate, to third-country nationals legally residing or legally staying in its territory. and Member States could accept such certificates. Ireland could also accept certificates issued by Member States to third-country nationals legally residing or legally staying in their territories.~~ **Ireland and the other Member States should mutually accept certificates issued to third country nationals covered by this Regulation based on reciprocity**.

(14) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen acquis within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession.

(15) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Council Decision 1999/437/EC[7].

(16) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/146/EC[8].

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6 Council Decision of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen acquis (OJ L 64, 7.3.2002, p. 20).

7 Council Decision of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen acquis (OJ L 176, 10.7.1999, p. 31).

8 Council Decision of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis (OJ L 53, 27.2.2008, p. 1).

(17) As regards Liechtenstein, this Regulation constitutes a development of provisions of the Schengen acquis within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1 point C, of Decision 1999/437/EC read in conjunction with Article 3 of Decision 2011/350/EU[9].

(18) The European Data Protection Supervisor and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European Parliament and of the Council[10] and delivered a~~n~~ **joint** opinion on **31 March 2021**,

HAVE ADOPTED THIS REGULATION:

Article 1

Member States shall apply the rules laid down in Regulation (EU) 2021/XXXX [Regulation on a Digital Green Certificate] to those third country nationals who do not fall within the scope of that Regulation but who reside or stay legally in their territory and are entitled to travel to other Member States in accordance with Union law.

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9 Council Decision of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

10 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Article 1a

Provided that Ireland has notified the Council and the Commission that it accepts certificates issued by Member States to persons covered by this Regulation, Member States shall accept, under the conditions of Regulation (EU) 2021/XXXX [Regulation on a Digital Green Certificate], certificates making up the Digital Green Certificate issued by Ireland to third country nationals who may travel freely within the territory of the Member States.

Article 2

This Regulation shall enter into force on**, and apply from,** the ~~third~~ day ~~following that~~ of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

eHealth Network

Guidelines on

COVID-19 citizen recovery interoperable certificates - minimum dataset

Release 1

2021-03-15

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth.

Adopted by the eHealth Network, 15 March 2021

The periods of infectiousness and protection mentioned in this guideline follow the ECDC Guidance and might undergo changes as new scientific evidence arises.

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1 Introduction

To date, the results of COVID-19 testing have been the principal factor to decide on implementation of measures, e.g. isolation/quarantine, cross-border movement, etc. Despite efforts for a common approach on free movement across the EU/EEA, citizens are still facing problems when trying to present test certificates issued by one Member States in another (issues include language used or lack of trust in the authenticity of the document). To facilitate free movement within EU/EEA Member States, a common certificate for COVID-19 testing is needed. With the rollout of the first COVID-19 vaccines on the EU market, there is also a desire from some Member States to introduce vaccination certificates for the purposes of free movement across borders. Under the proposal for a Digital Green Certificate, a framework for interoperable certificates on COVID-19 vaccination, testing and recovery should be established.

The guideline follow epidemiological guidance[1] and the specific values will be provided in due time by relevant institutions.

2 Use case – COVID-19 citizen recovery

According to the current evidence, individuals who recover from COVID-19 can continue to test positive for SARS-CoV-2 for some time after no longer being infectious. In those cases, the virus being shed is no longer viable and there is therefore limited risk of transmission to others. However, for the purposes of free movement, those individuals are unable to present a negative test result, and would thus be prevented from crossing borders. However, despite some uncertainties (described in the following chapter), on balance the evidence suggests that those who have recovered from COVID-19 have a reduced risk of infection.

[1] https://www.ecdc.europa.eu/en/publications-data/covid-19-guidance-discharge-and-ending-isolation

2.1 Scientific unknowns

Some scientific unknowns remain regarding the infectiousness of a person infected with COVID-19. The following aspects are of particular relevance:

- there is insufficient information on levels of immunity conferred by previous infection. It is widely accepted that previous infection provides in general some reduced risk of subsequent infection, but there is a lack of consensus on how much reduced risk of infection, the length of the protection and the extent of variation between individuals.

- although relatively uncommon, reinfection in persons recently recovered from COVID-19 has been documented. It has been reported that up to 9% of PCR positive cases do not mount an antibody response and may be susceptible for reinfection and further transmitting disease. More recently, possible reinfections with emerging variant strains such as B.1.351 and P.1 are of special concern.

- the exact duration of the protection conferred by a previous infection, in particular in view of the increased transmission in EU/EA MSs of the new variants of concern, should be revised as new evidence is collected.

Due to the current unknowns, the validity of certificates might undergo changes according to new scientific evidence. Considering the emergence of SARS-CoV-2 variants, this epidemiological evidence may change and ECDC, the Commission and Member States should take all the measures to update all the relevant guidance, legal acts and IT systems.

3 Minimum dataset

A minimum dataset, including a unique identifier, enables minimum information to be generated according to a common agreed structure, facilitating cross-border sharing and use.

Table 1 – COVID-19 citizen recovery minimum dataset

Section	Data element	Description	Preferred Code System
Person identification	Person name	The legal name of the person recovered from the infection surname(s) and forename(s) in that order	
	Person date of birth	Recovered person's date of birth.	Complete date, without time, following the ISO 8601.

	Person identifier (optional)	The type of identifier and identifier of the person, according to the policies applicable in each country. Examples: citizen ID and/or document number (ID-card/passport)	
Information about past infection	Disease or agent	Disease or agent the citizen has recovered from	ICD-10, SNOMED CT GPS
	Date of first positive test result	Date when the sample for the test was collected that led to positive test obtained through a procedure established by a public health authority in the MS [specific rules to be determined later]	Complete date, without time, following the ISO 8601.
	Country of test	Country in which the first positive test was performed	ISO 3166 Country Codes
Certificate metadata	Certificate issuer	Entity that has issued the certificate (allowing to check the certificate)	
	Certificate Identifier	Unique identifier of the certificate to be printed into the certificate; the way of defining it should be similar to the vaccination guidelines[2]	
	Certificate valid from	Certificate valid from [specific rules to be determined later] *Subject to change as new evidence arises*	ISO 8601 or other international stated format

[2] https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

	Certificate valid until	Certificate valid until [specific rules to be determined later] *Subject to change as new evidence arises*	ISO 8601 or other international stated format

All fields that contain non-enumeration/numeric data should be encoded in UTF-8 must be fully canonicalised and normalised according to http://unicode.org/reports/tr15/

4 Further steps towards cross-border interoperability

The guidelines on *COVID-19 Citizen Recovery interoperable certificates - minimum dataset* will be followed by further steps towards cross-border interoperability of COVID-19 certificates.

In close cooperation with ECDC and WHO and supported by the European Commission, the eHealth Network and the Health Security Committee will continue working towards the design and implementation of interoperable solutions that work across borders and world regions.

In addition, the European Commission is invited to support the development of toolboxes and trust frameworks to facilitate the deployment of interoperable solutions.